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| 10/595,329 | 06/14/2007 | Darrell H. Reneker | 113129.0001.US | 7593 |
| 39905 7590 08/03/2009 ROETZEL AND ANDRESS 222 SOUTH MAIN STREET AKRON, OH 44308 | | | | |
| EXAMINER MEDWAY, SCOTT J | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/595,329

Applicant(s)

RENEKER ET AL.

Examiner

SCOTT MEDWAY

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
4a) Of the above claim(s) 5-11 and 15-30 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4 and 12-14 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 10 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date 06/16/2006
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 5-11 and 15-30 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall not serve as a basis for any other multiple dependent claim. See 37 CFR 1.75c and MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 1-4 and 12-14 are currently pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 1, 3 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Weber (U.S. Pub. 2003/0065355 A1).**

Examiner notes that several limitations of Applicants' apparatus claims recites a product-by-process limitation. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. See MPEP

2113. At least the following phrases recite a product-by-process limitation: "the outer surface layer being made from electrospun nanofibers" (claim 1, line 2); "the intermediate layer being formed by dip coating" (claim 2, line 2); " the outer surface layer is formed on a separate flexible tube and the outer surface layer is slipped over the balloon" (claim 3, lines 1-2).

Regarding claims 1, 3 and 12, Weber discloses an expandable balloon capable of use in angioplasty procedures (para [0067]); comprising a balloon having an outer surface layer being made from nanofibers deposited by electrospinning (para [0032]) and incorporating at least one pharmaceutically active substance (para [0037]).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber (U.S. Pub. 2003/0065355 A1) in view of Michael et al (U.S. Pub. 2003/0153943 A1, hereinafter "Michael").

Regarding claim 2, it is noted that Weber does not disclose an intermediate layer. Michael discloses an expandable balloon capable of use in angioplasty procedures, comprising an outer surface made of spun nanofibers and having an intermediate layer disposed beneath the outer layer and being formed by dip coating (paras [0165]-[0171]). It would have been obvious for one of ordinary skill in the art at the time of the invention to form an intermediate layer as taught by Michael in the device of Weber since such a layer is well-known for use in constructing balloons and can be used to provide an enhanced reinforcement in the balloon.

8. **Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weber (U.S. Pub. 2003/0065355 A1) in view of Leeftang et al (U.S. Pat. 6,635,070 B2, hereinafter "Leeftang").**

Regarding claim 4, it is noted that Weber does not disclose the flexible tube defining a spoke-and-hub formation when folded. Leeftang discloses an expandable balloon capable of use in angioplasty, comprising a folded configuration having a spoke-and-hub formation (see Fig. 9B). Since Weber discloses folding the balloon, choosing a spoke-and-hub formation according to the teaching of Leeftang is considered well known at the time of the invention for optimally compressing the device for easy insertion into a body vessel.

9. **Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weber (U.S. Pub. 2003/0065355 A1) in view of Wang et al (U.S. Pat. 5,490,839).**

It is noted that Weber does not disclose the outer surface layer being applied in the unexpanded state of the balloon. Wang discloses coating a balloon with an outer surface layer when the balloon is in its unexpanded state (col. 6, lines 21-23). It would have been obvious for one of ordinary skill in the art at the time of the invention to contemplate coating a balloon's outer surface in its unexpanded state so as to ensure that the coating is applied such that the balloon can fit through its intended passage, e.g. a vessel or a protective sheath, prior to expansion.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ramakrishina et al (see "*Electrospun Polymer Nanofibers and their Potentials*", February 2003) discloses that it is well known to coat medical balloons with electropsun nanofibers.

Applicant is additionally directed to the *Notice of References Cited*.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 7:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit: 3763

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/Scott J. Medway/
Examiner, AU 3763
07/31/2009

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763